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EXAMINER

NOLAN, PATRICK J

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 08/11/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,809

Applicant(s)

EISENBERG ET AL.

Examiner

Patrick J. Nolan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 1-29, 48, 49 and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-43, 47 and 50 is/are rejected.
- 7) ☒ Claim(s) 44-46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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1. This application is a 35 USC 371 of PCT/IL00/00346.
2. Claims 1-51 are pending.
3. Applicant's election with traverse of Group II, claims 30-47 and 50 in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the prior art did not teach any in vivo data and so was not enabled. This is not found persuasive because under 35 USC 112 1st paragraph for a reference to be enabling it need to teach how to make and use, which the prior art patent does do.
The requirement is still deemed proper and is therefore made FINAL.
Claims 1-29, 48-49 and 51 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.
4. Applicant needs to insert the SEQ ID NOS in the specification and claims for sequence rules compliance.
5. Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 lacks antecedent basis in base claim 31 for the peptide.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 30-43 are rejected under 35 U.S.C. § 103 as being unpatentable over Kuby et al., (U), in view of Aridor et al. (V), and U.S. Patent 5,807,746 (A).

Kuby et al., teaches that inhibition of mast cell degranulation is a known mechanism to treat allergies. The claimed invention differs from the prior art teachings by the recitations of using a cell importation peptide linked to a mast cell degranulation inhibitor peptide to treat allergies.

However, Aridor et al., teaches the peptide KNNLKECGLY and its use in inhibiting mast cell degranulation when it was given to cells that were permeabilized. In addition Aridor teaches that said peptide was ineffective in inhibiting mast cell degranulation when it was added to intact cells. The '746 patent teaches adding the sequence AAVALLPAVLLALLAP to any known biologically active peptide to allow the transportation of said peptide to the inside of the cell, since the permeabilization of cells for peptide entry is only practical for ex vivo therapy, while using importing peptides allows for in vivo therapies. The '746 patent teaches administering said peptides orally, wherein the transportation peptide is peptide bound to the biologically active peptide.

One of ordinary skill in the art at the time the invention was made would have been motivated to add the importation peptide taught by the '746 patent to the mast cell degranulation inhibitor peptide taught by Aridor et al., because treating allergies with mast cell degranulation inhibitors was well known in the art as taught by Kuby et al., and Aridor et al.'s peptide suffered from not being useful due to its inability to be transported across the cell membrane, a deficiency cured by the teachings of the '746 patent. From the teachings of the

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references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

7. Claims 30, 31 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuby et al., in view of Aridor et al., and US Patent 5,807,746 as applied to claims 30 and 31 above, and further in view of US Patent 6,103,692.

The Kuby et al., Aridor et al., and '746 patent have been discussed supra. The claimed invention differs from the prior art teachings from the recitation of adding succinylation to the peptide.

However, the '692 patent teaches that succinylation of peptides increases the ability of the peptide to pass through the cell membrane and into the cell.

Therefore one of skill in the art would have been motivated to succinylate the peptide made obvious by Kuby et al., Aridor et al., and the '746 patent, because succinylation increases transport through the cell membrane, a necessary feature for mast cell degranulation inhibitory peptide as taught by Aridor et al. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.


8. Claims 44-46 are free of the prior art as of the last search.

9. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Thursday from 9:30 am to 4:30 pm.

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11. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 872-9306. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.


Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
8/6/03